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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,543

08/30/2006

Robert J. Watts

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7590

04/29/2008

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
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BOSTON, MA 02111

EXAMINER

ROBINSON, JAMES MARSHALL

ART UNIT

PAPER NUMBER

4148

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,543	Applicant(s) WATTS, ROBERT J.	
	Examiner James M. Robinson	Art Unit 4148	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 19-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 October 2005 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/30/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 19-21, 23-25, 28, 30-36** are rejected under 35 U.S.C. 102(b) as being anticipated by **Philipp (US 4559934)**.

Regarding claim 19, Philipp discloses an ankle-foot orthosis for resisting plantarflexion of a patient's foot, the orthosis comprising an elastic structure (col. 4, lines 24-25) formed of contiguous first and second tubular members (fig. 1), said second tubular member being set at an angle to the first tubular member to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle (fig. 1) of the patient; and a rib (7) which is permanently bonded or otherwise permanently affixed (col. 4, lines 42-44) to a region of the structure which overlies the dorsum (col. 2, lines 30-35) of the patient's foot in use, the rib being formed of a resiliently flexible material (col.4, lines 39-42) that has a resilience appropriate for resisting the particular degree of plantarflexion experienced by the patient.

Regarding claim 20, Philipp discloses an orthosis wherein the elastic structure is operable to exert a compressive force on said foot and ankle of said patient (col. 4, lines 24-25).

Regarding claim 21, Philipp discloses an orthosis wherein the elastic structure comprises a compression stocking (1).

Regarding claim 23, Philipp discloses an orthosis wherein the compressive force is more or less than at least 5 mm Hg (approximately 670 Pascals)

Regarding claim 24, Philipp discloses an orthosis wherein different regions of the elastic structure exert different compressive forces on the foot and ankle of the patient (4, 15, reinforced areas of the orthosis create different compressive forces on the foot and ankle of the patient).

Regarding claim 25, Philipp discloses an orthosis wherein a second tubular member (or at least a portion of said second tubular member) exerts a greater compressive force on the foot (4) than the compressive force exerted on the ankle by the first tubular member (col. 3, lines 12-14).

Regarding claim 28, Philipp discloses an orthosis wherein the resilience of the rib (7), as between a first orthosis and a second orthosis, may be varied by varying the composition of the rib of one orthosis as compared to the other (col. 4, lines 39-42; Philipp discloses that the plate made of an elastically yielding material, for example, a plastic or steel, this range of materials would inherently vary the resilience of the rib/plate).

Regarding claim 30, Philipp discloses an orthosis wherein a rib comprises a pair of proximal wings (18) extending from the rib towards the back of the ankle of the patient (fig. 3).

Regarding claim 31, Philipp discloses an orthosis wherein proximal wings (18) extend in parallel to a proximal edge of the elastic structure (fig. 1).

Regarding claim 32, Philipp discloses an orthosis wherein the proximal wings (18) have the same resilience or a different resilience to that of the rib (the proximal wings are made of the same material as the rest of the plate, therefore inherently have the same resilience as the rest of the plate).

Regarding claim 33, Philipp discloses an orthosis wherein a rib comprises a pair of distal wings (17) extending from the rib (7), in the region of the metatarsal heads, towards the plantar aspect of the foot (fig. 1).

Regarding claim 34, Philipp discloses an orthosis wherein distal wings (17) extend generally in parallel to a distal edge of the elastic structure (fig. 1).

Regarding claim 35, Philipp discloses an orthosis wherein distal wings (17) have the same resilience or a different resilience to that of the rib (the distal wings are made of the same material as the rest of the plate, therefore inherently have the same resilience as the rest of the plate).

Regarding claim 36, Philipp discloses an orthosis wherein a rib (7) comprises a pair of proximal wings (18) extending from the rib towards the back of the ankle of the patient, and further comprises a pair of distal wings (17) extending from the rib, in the region of the metatarsal heads, towards the plantar aspect of the foot

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Philipp (US 4559934)** in view of **Gardon-Mollard et al. (US 6430970)**.

Regarding claims 22, Philipp discloses an orthosis according wherein the elastic structure is woven to provide an elastic stretch (col. 4, lines 24-25), a stretch that increases the cross-sectional area of said generally L-shaped cavity.

Philipp fails to disclose that the elastic stretch is only in one direction and that the compressive force of the elastic structure is more or less than at least 5 mm Hg (approximately 670 Pascals).

However, Gardon-Mollard discloses a compressive orthosis (such as retention stockings) in which there is a greater elastic return force in the horizontal direction than in the vertical direction (col. 4, claim 6), and that the compressive force of the elastic structure is more or less than at least 5 mm Hg (approximately 670 Pascals) (col. 2, lines 13-24).

To provide the device of Philipp with an elastic structure woven to provide an elastic stretch in one direction with a compressive force of more or less than at least 5 mm Hg would have been obvious to one of ordinary skill in the art, in view of the teachings of Gardon-Mollard, since all the claimed elements were known in the prior art and one skilled in the art could have combine the elements as claimed by known methods with no change in their respective functions. The combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the

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time of the invention, i.e., one skilled in the art would have recognized that the material of Gardon-Mollard would allow the orthosis of Phillip to achieve unidirectional compression.

5. **Claims 26, 29, & 38** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Philipp (US 4559934)** in view of **Billotti (US 5378224)**.

Regarding claims 26 & 29, Philipp discloses an orthosis wherein the rib (7) is made of an elastically yielding material for example a plastic (col. 4, lines 39-40).

Philipp fails to disclose the rib is of silicone elastomer of 35 to 80 shore silicone elastomer, preferably 65 shore silicone elastomer.

However Billotti discloses an orthosis for supporting a foot and ankle (fig. 15) comprising a flexible sheet (32) formed of an elastomer such as a silicone (col. 4, lines 6-8). The silicone elastomer utilized is flexible and within the range of hardness of 35 to 80 shore silicone elastomer.

To provide the device of Philipp with a rib made of silicone elastomer of 35 to 80 shore silicone elastomer would have been obvious to one of ordinary skill in the art, in view of the teachings of Billotti, since all the claimed elements were known in the prior art and one skilled in the art could have combine the elements as claimed by known methods with no change in their respective functions. The combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that the material of Billotti would allow the orthosis of Phillip to achieve appropriate forefoot elevation.

Regarding claim 38, Philipp discloses an ankle-foot orthosis for resisting plantarflexion of a patient's foot (col. 2, lines 14-16), the orthosis comprising: an elastic compression stocking (1) formed of contiguous first and second woven elastic tubular members(fig. 1), said second tubular member being set at an angle to the first tubular member to define, at least in use, an L-shaped cavity (FIG. 2) configured to accept and fit closely about the foot and ankle of the patient; a rib (7) permanently affixed (col. 4, lines 42-44) to a region of the stocking which overlies the dorsum of the patient's foot (col. 2, lines 30-35) in use, wherein the rib is configured and arranged to provide a resistance to plantarflexion (col.4, lines 39-42) that is appropriate for resisting the particular degree of plantarflexion experienced by the patient, and wherein the rib further comprises a pair of proximal wings(18) extending from the rib towards the back of the ankle of the patient (fig. 1), and a pair of distal wings (17) extending from the rib, in the region of the patient's metatarsal heads, towards the plantar aspect of the foot (fig. 1).

Philipp fails to disclose that the rib is silicone.

However Billotti discloses an orthosis for supporting a foot and ankle (fig. 15) comprising a flexible sheet (32) formed of an elastomer such as a silicone (col. 4, lines 6-8).

To provide the device of Philipp with a rib made of silicone would have been obvious to one of ordinary skill in the art, in view of the teachings of Billotti, since all the claimed elements were known in the prior art and one skilled in the art could have combine the elements as claimed by known methods with no change in their respective

functions. The combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention, i.e., one skilled in the art would have recognized that the material of Billotti would allow the orthosis of Phillip to achieve appropriate forefoot elevation.

6. **Claims 27 & 37** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Philipp (US 4559934)**.

Regarding claim 27, Philipp discloses a resilient rib (7) permanently secured to an orthosis.

Philipp fails to disclose the resilience of the rib may be varied by varying the thickness of the rib.

It would have been obvious to one of ordinary skill in the art at the time of the invention that rib resiliency is correlated to the thickness of the rib. Varying thickness of a material in order to alter its resiliency is well known and conventional in the art.

Regarding claim 37, the method of manufacture of the device of Philipp incorporates the claimed method steps including:

providing an elastic structure formed of contiguous first and second tubular members set at an angle to one another to define, at least in use, a generally L-shaped cavity configured to accept and fit closely about the foot and ankle of a patient; mounting the structure on a foot-shaped anvil ; preparing a silicone elastomer having a resilience which is appropriate for resisting the particular degree of plantarflexion experienced by the patient; applying the silicone elastomer to the elastic structure to form a rib that will in use overlie the

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dorsum of the patient's foot; allowing the silicone elastomer to cure; and removing the elastic structure from the anvil.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize manufacturing techniques in this manner to achieve the claimed orthosis. These manufacturing methods are well known and conventional in the art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Fisher (US 7354413), Scott (US 7125392), Watts (US 6908445), Strassburg (US 5399155), Mance (US D350204).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James M. Robinson whose telephone number is (571) 270-3867. The examiner can normally be reached on Mon-Fri 7:30 AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrell McKinnon can be reached on (571)272-4797. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James M. Robinson

April 21, 2008

/Terrell L Mckinnon/

Supervisory Patent Examiner, Art Unit 4148

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